(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 554 082 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
29.12.1997 Bulletin 1997/52

(51) Int. Cl.[6]: **A61F 2/06**, A61M 29/00

(21) Application number: **93300610.8**

(22) Date of filing: **28.01.1993**

(54) Expandable stent

Expandierbarer Stent

Dilatateur expansible

(84) Designated Contracting States:
BE CH DE FR GB IT LI NL

(30) Priority: **31.01.1992 US 830219**

(43) Date of publication of application:
04.08.1993 Bulletin 1993/31

(60) Divisional application:
96202442.8 / 0 749 730

(73) Proprietor:
ADVANCED CARDIOVASCULAR SYSTEMS, INC.
Santa Clara California 95052 (US)

(72) Inventor: **Williams, Michael S.**
Cupertino, California 95014 (US)

(74) Representative:
Mayes, Stuart David et al
BOULT WADE TENNANT,
27 Furnival Street
London EC4A 1PQ (GB)

(56) References cited:
EP-A- 0 335 341
EP-A- 0 364 787
EP-A- 0 420 541
US-A- 4 740 207
US-A- 4 969 896
US-A- 5 007 926

EP 0 554 082 B1

Printed by Xerox (UK) Business Services
2.15.7/3.4

Description

BACKGROUND OF THE INVENTION

Field Of The Invention

The present invention generally relates to expandable endoprosthesis devices, in particular expandable intraluminal vascular grafts, generally called stents, which are adapted to be implanted into a patient's lumen, such as a blood vessel, to maintain the patency of the vessel. These devices are frequently used in the treatment of atherosclerotic stenosis in blood vessels, especially after percutaneous transluminal coronary angioplasty (PTCA) procedures, to prevent restenosis of a blood vessel. The present invention also relates to an expandable intraluminal vascular graft that can be used in any body lumen, and can be used for drug delivery.

Description Of Related Art

In expandable stents that are delivered with expandable catheters, such as balloon catheters, the stents are positioned over the balloon portion of the catheter and expanded from a reduced diameter to an enlarged diameter greater than or equal to the artery wall, by inflating the balloon. Stents of this type can be expanded and held in an enlarged diameter by deformation of the stent (e.g., U.S. Patent No. 4,733,665 to Palmaz), by engagement of the stent walls with respect to one another (e.g., U.S. Patent No. 4,740,207 to Kreamer; U.S. Patent No. 4,877,030 to Beck et al.; and U.S. Patent No. 5,007,926 to Derbyshire on which the first part of claim 1 is based), and by one-way engagement of the stent walls together with endothelial growth into the stent (e.g., U.S. Patent No. 5,059,211 to Stack et al.).

SUMMARY OF THE INVENTION

According to the present invention there is provided an expandable intraluminal stent implantable in a vessel, comprising: a body portion; a plurality of protrusions, said protrusions projecting from said body portion; and a plurality of apertures in said body portion, several of said protrusions engaging said apertures and several of said protrusions, engaging said vessel to retain said intraluminal stent with respect thereto, characterised in that the protrusions are cut away from the body portion, the parts of the body portion thus removed defining the apertures.

Preferred embodiments of the present invention provide a stent that is capable of localized therapeutic drug delivery.

Still other preferred embodiments f the present invention provide a stent that is bioabsorbable.

These and other embodiments of the invention will become more apparent from the following detailed description thereof when taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 shows a perspective view of one embodiment of the present invention, showing a stent in a non-expanded form.

Fig. 2 shows an axial view of another embodiment of the present invention, employing shallower dimensioned protrusions.

Fig. 3 shows the dimensions of the protrusions in Fig. 2.

FIG. 4 shows an axial view of a third embodiment of the present invention, employing a random dispersion of protrusions.

DETAILED DESCRIPTION OF THE INVENTION

As shown by the embodiment of Fig. 1, a stent 10 is formed, in its natural state prior to expansion, in a cylinder having protrusions or teeth 15 on one side of the stent, forming a roughened outer wall or exterior surface 5 that is adapted to lie contiguous with an arterial wall. Teeth 15 of roughened outer wall or exterior surface 5 of stent body 10 are designed to engage the arterial walls and endothelium layer of a blood vessel, and, in general, would engage the walls of a body lumen to help retain the stent in place.

The teeth 15 are cut away from a sheet of material which is then curled into a cylinder. The cylinder has a wall thickness 25 at its end. In the embodiment of Fig. 2 the wall thickness of the stent tapers towards the ends, to form a beveled end surface, to give greater flexibility and vessel compliance to the stent, as explained below.

Apertures 20 correspond to the recesses of body 10 left behind when teeth 15 were cut away from the body. Apertures 20 thus have the same outline as teeth 15.

As can be seen in the Fig. 1 embodiment, teeth 15 are arranged in rows extending axially (longitudinally) along the stent body, and have a sharp, narrow "V" shape. Although in this embodiment a sharp "V" shape is employed, in general, practically any shaped protrusion may be employed. The teeth create a roughened surface texture on the stent body.

Furthermore, while in all the embodiments shown the protrusions are found on one side of the stent body, namely the outer wall of the stent body or the side lying against the artery, it is possible to have protrusions or projections on either or both sides of the body.

In the embodiment of Fig. 1, teeth 15 project out from the exterior surface or roughened outer wall 5 of stent body 10, the side adjacent to the artery wall. The teeth can thus engage th stent wall in a positive manner. The interior surface or inner wall 6 of stent body 10 is the side facing the bloodstream, and is substantially

free of any projections.

In the preferred embodiment shown in Fig. 1, the teeth are formed from stent body 10 in a one-piece or unitary manner, being cut from the same sheet of material that constitutes the stent body. The portion of the stent body thus removed becomes a tooth or protrusion, leaving an aperture 20 in the body having substantially the same shape as the tooth. Apertures 20 are thus defined by the portion of the stent body removed to form the teeth or protrusions. The teeth may be formed by injection-molding, casting, lasing, etching, plasma and corona techniques, or machining.

Also in the preferred embodiment of Fig. 1, stent body 10 is formed from a sheet of material curled into a cylinder, with the sheet having overlapping edges, as can be seen in Fig. 1. Also, and as is readily apparent from Fig. 1, the overlapping edges allow the exterior surface or outer wall 5 to contact the interior surface or inner wall 6 of the cylinder forming the stent. The protrusions 15 on the outer wall, which make the outer wall rougher than the inner wall, permit the outer wall to engage the apertures in the inner wall, and, together with the engagement of the protrusions with the blood vessel, hold the stent in place in an enlarged diameter form in the patient's vasculature.

While in the preferred embodiments disclosed herein protrusions 15 were formed from the body in the form of triangular teeth, in general, the protrusions may be formed in any shape and in any manner, including by adding the protrusions to a smooth stent body made of the same or different material from the protrusions, or treating the stent body to create a roughened surface texture, which texture can be with or without apertures in the stent body.

Furthermore, while any material may be employed to form the stent of the present invention, preferably a Food and Drug Administration (FDA) approved material for use in this environment is employed, that is, a biocompatible material. Metals such as stainless steel, Ni-Ti, platinum (Pt), Nitinol (Nitinol is a trade mark of Minnesota Mining and Manufacturing Company), Tantalum (Ta) or gold (Au) may be used.

A plastic that is biocompatible may be used. The biocompatible plastic may also be bioabsorbable, that is, biodegradable. For instance, a polymer from the linear aliphatic polyester family, such as poly(lactic acid), poly(glycolic acid) or polycaprolactone, and their associated copolymers, may be employed. Degradable polymers such as polyorthoester, polyanhydride, polydioxanone and polyhydroxybutyrate may also be employed.

When the stent is expanded by an expanding device, such as a balloon catheter, teeth 15 engage apertures 20 to lock the stent open in an expanded diameter form. A plurality of teeth 15 hold the stent in an expanded diamet r form by engaging apertures 20 and the arterial walls. By engaging the arterial walls, teeth 15 on roughened outer wall 5 also prevent the stent from being axially displaced along the artery.

Expansion of stent 10 from a reduced diameter form into an expanded diameter form is preferably performed by a balloon catheter. Any other means for expanding the stent, however, may be used. Briefly, and in general terms, when the stent is to be deployed in a coronary artery the stent is placed over a balloon catheter that has been prepared for PTCA angioplasty. The catheter is percutaneously introduced into a vessel, following a previously positioned guidewire in an over-the-wire angioplasty catheter system, and tracked by a fluoroscope, until the balloon portion and associated stent are positioned at the point where the stent is to be placed. Thereafter, the balloon is inflated and the stent is expanded by the balloon portion from a reduced diameter form to an expanded diameter form. After the stent has been expanded to its final expanded diameter, the balloon is deflated and the catheter is withdrawn, leaving the stent in place.

It should be understood that the present stent is not limited to use in coronary arteries and over-the-wire angioplasty catheter systems, but the stent may be deployed in any body lumen by any suitable mechanical means, which includes hydraulic expansion.

To facilitate the placement of a stent embodying the present invention, the stent may be impregnated with a radiopaque material, making it opaque, and, therefore, visible, to X-rays. Suitable radiopaque materials include iodine-based materials and solutions thereof, and barium salts, including materials containing iodipamide (sold commercially under the trade name Cholografin), iopanoic acid (sold under the trade name Telepaque), barium sulfate, bismuth trioxide, bismuth oxychloride, or powdered metals, such as tantalum, gold, platinum and palladium.

It is further envisioned that the stent may be impregnated with a therapeutic agent to provide localized drug delivery.

When the stent has been expanded to its final form, the stent is affixed in place by a combination of the teeth in the body engaging apertures in the body of the stent, as well as the teeth engaging the walls of the artery, including the endothelium layer. It is believed that the endothelium layer of the artery will grow into the stent over a short period of time (in 7 to 21 days), to further help retain the stent in place. The stent may be made of a bioabsorbable material, such as any of the materials disclosed above, so that eventually the stent will dissolve. Endothelium layer growth into the stent and the modified surface texture of the stent ensures that pieces of the stent will not discharge into the bloodstream and cause an embolism as the stent is dissolved.

It can be seen that one of the features of the described embodiment includes maintaining an expandable stent in an enlarged diameter or operative form in a body lumen, by providing a roughened surface texture on the outside surface of the stent that engages both the lumen wall and the stent itself.

Turning now to Fig. 2, a protrusion pattern for a second embodiment of the present invention is disclosed. The stent of the second embodiment substantially corresponds in structure to the embodiment disclosed in Fig. 1, the principle difference being the geometric shape and spacing of the teeth, and the beveling of the ends, to be described below. In the Fig. 1 embodiment teeth 15 form a sharp, narrow "V" shape, whereas in the second embodiment teeth 15 are less pointed, and form a wider "V" shape. As shown in Fig. 3, height 35 of the apex of the "V" is 2.54×10^{-4}m (0.010 in), width 40 at the mouth of the "V" is 5.08×10^{-4}m (0.020 in)., and the length of side 45 is 3.556×10^{-4}m(0.014 in). Sides 50 of each tooth are spaced at 90° to one another at the apex. The teeth are spaced along the circumference of the stent in rows, each row spaced 4.801×10^{-4}m (0.0189 in) from one another, as indicated by reference No. 57.

As can be seen in Fig. 2, another modification of the stent of the second embodiment is the presence of beveled ends 55. As can be seen from the drawings, beveled ends 55 are defined as those portions of the cylindrical stent that lie along the longitudinal (axial) axis of the cylinder, spaced from one another by approximately the longitudinal length of the stent. Beveled ends 55 allow the stent to be more compliant and flexible at its ends, so that the ends can more easily match the flexibility of the vessel walls that the stent is embedded in, and allow the stent to be more vessel compliant. Beveled ends 55 taper from a larger wall thickness away from the ends to a smaller wall thickness at the very end of the stent, as can be seen from the drawing. For instance, on the right hand side the stent is beveled along a portion of the stent starting from point 65, defining the right hand end of the stent, to 75. In a symmetrical fashion the left hand side of the stent end is beveled, with both beveled ends having an angulation θ. As is readily apparent the wall thickness of the stent along the beveled portion is less than the wall thickness of the stent outside the beveled portion.

The height of the bevel from points 60 and 65 is 1.397×10^{-3}m (0.055 in), while the length of the straight portion of the stent from points 70 and 75 is 0.012m (0.455 in), with the overall length from end to end being 0.015m (0.600 in).

Another embodiment of the present invention is shown in Fig. 4. In this embodiment, the tooth pattern is substantially random, with protrusions 71 scattered throughout the body of the stent, which is formed from a sheet curled into a cylinder, as in the other embodiments. The operation of this embodiment of stent is the same as the other embodiments, with the teeth engaging apertures in the body, as well as engaging the walls of the vessel the stent resides in, when the stent is expanded into an enlarged diameter form.

The surface texture forming the protrusions may be formed via plasma techniques, c rona techniques, molding, casting, lasing, etching, machining, or any other technique that changes the surface texture of the body.

Furthermore, it should be understood that the dimensions set forth for the above embodiments are not intended to limit the invention to only those dimensions. For example, while certain dimensions might be appropriate for a stent used in a coronary artery, these same dimensions might not be suitable for a stent used in other parts of a patient's vasculature or body lumen.

Claims

1. An expandable intraluminal stent (10) implantable in a vessel, comprising:

   a body portion;
   a plurality of protrusions (15), said protrusions (15) projecting from said body portion; and
   a plurality of apertures (20) in said body portion, several of said protrusions (15) engaging said apertures (20) and several of said protrusions (15) engaging said vessel to retain said intraluminal stent (10) with respect thereto, characterised in that the protrusions (15) are cut away from the body portion, the parts of the body portion thus removed defining the apertures (20).

2. The intraluminal stent of claim 1, wherein:

   said body portion has an exterior surface implantable adjacent a wall of said vessel, and said protrusions (15) project from said exterior surface of said body portion.

3. The intraluminal stent of claim 1 or claim 2, wherein said protrusions (15) are unitary with said body portion and have a substantially "V" shape, said apertures (20) having substantially the shape of said protrusions (15).

4. The intraluminal stent of claim 3, wherein said protrusions (15) have sides of substantially equal length that form an apex, with said sides spaced by an angle of about 90° at said apex.

5. The intraluminal stent of any preceding claim, wherein said protrusions (15) are spaced at about 4.801×10^{-4}m (0.0189 inches) to one another, and have sides which are about 3.556×10^{-4}m (0.014 inches) in length.

6. The intraluminal stent of any preceding claim, wherein said stent is formed of a plastic selected from the group consisting of a polymer selected from the linear aliphatic polyester family and their associated copolymers.

7. The intraluminal stent of any preceding claim,

wherein said protrusions (15) are spaced from one another in a substantially uniform manner, to form rows of protrusions (15).

8. The intraluminal stent of any of claims 1 to 6, wherein said protrusions (15) are randomly dispersed throughout said body portion.

9. The intraluminal stent of any preceding claim, wherein said body portion is made of a material formed into a cylinder.

10. The intraluminal stent of claim 9, wherein said material is bioabsorbable.

11. The intraluminal stent of claim 9 or claim 10, wherein said material is a polymer selected from the group consisting of polylactic acid, polyglycolic acid, polycaprolactone, and their associated copolymers.

12. The intraluminal stent of any of claims 1 to 9, wherein said body portion is made of a material which is biocompatible and selected from the group consisting of the linear aliphatic polyester family, polyorthoester, polyanhydride, polydioxanone, polyhydroxybutyrate, stainless steel, nickel-titanium, platinum, Nitinol, tantalum and gold.

13. The intraluminal stent of any preceding claim, wherein said body portion is made of a material containing a therapeutic agent.

14. The intraluminal stent of any preceding claim, wherein said body portion is made of a material formed into a cylinder having a longitudinal axis and two ends (55) spaced along said longitudinal axis, said ends (55) being beveled to allow said stent (10) to be more flexible at said ends (55).

15. The intraluminal stent of any preceding claim, wherein said body portion is made of a material which is radiopaque.

Patentansprüche

1. Expandierbarer Intralumen-Stent (10), welcher in ein Gefäß implantierbar ist, umfassend:

einen Körperabschnitt,
eine Mehrzahl von Vorsprüngen (15), wobei die Vorsprünge (15) von dem Körperabschnitt hervorstehen, und
eine Mehrzahl von Öffnungen (20) in dem Körperabschnitt, wobei einige der Vorsprünge (15) in die Öffnungen (20) eingreifen und einige der Vorsprünge (15) an dem Gefäß angreifen, um den Intralumen-Stent (10) bezüglich diesem zu halten,
dadurch gekennzeichnet, daß die Vorsprünge (15) aus dem Körperabschnitt ausgeschnitten sind, wobei die somit entfernten Abschnitte des Körperabschnitts die Öffnungen (20) bilden.

2. Intralumen-Stent nach Anspruch 1, worin der Körperabschnitt eine benachbart einer Wandung des Gefäßes implantierbare Außenoberfläche aufweist und die Vorsprünge (15) von der Außenoberfläche des Körperabschnitts hervorstehen.

3. Intralumen-Stent nach Anspruch 1 oder Anspruch 2, worin die Vorsprünge (15) mit dem Körperabschnitt einteilig sind und im wesentlichen eine "V"-Form aufweisen, wobei die Öffnungen (20) im wesentlichen die Form der Vorsprünge (15) aufweisen.

4. Intralumen-Stent nach Anspruch 3, worin die Vorsprünge (15) Seiten mit im wesentlichen gleicher Länge aufweisen, welche einen Scheitel bilden, wobei die Seiten an dem Scheitel zueinander einen Winkelabstand von ungefähr 90° aufweisen.

5. Intralumen-Stent nach einem der vorhergehenden Ansprüche, worin die Vorsprünge (15) zueinander einen Abstand von ungefähr $4{,}801 \times 10^{-4}$m (0,0189 Zoll) aufweisen und Seiten aufweisen, welche eine Länge von ungefähr $3{,}556 \times 10^{-4}$m (0,014 Zoll) aufweisen.

6. Intralumen-Stent nach einem der vorhergehenden Ansprüche, worin der Stent aus einem Kunststoff gebildet ist, der aus der Gruppe ausgewählt ist, die ein Polymer umfaßt, das aus der Familie der linearen aliphatischen Polyester und deren zugeordneten Copolymeren ausgewählt ist.

7. Intralumen-Stent nach einem der vorhergehenden Ansprüche, worin die Vorsprünge (15) zueinander in einer im wesentlichen gleichförmigen Art und Weise im Abstand angeordnet sind, um Reihen von Vorsprüngen (15) zu bilden.

8. Intralumen-Stent nach einem der Ansprüche 1 bis 6, worin die Vorsprünge (15) über den Körperabschnitt hinweg regellos verteilt sind.

9. Intralumen-Stent nach einem der vorhergehenden Ansprüche, worin der Körperabschnitt aus einem zu einem Zylinder geformten Material gebildet ist.

10. Intralumen-Stent nach Anspruch 9, worin das Material bioabsorbierbar ist.

11. Intralumen-Stent nach Anspruch 9 oder Anspruch 10, worin das Material ein Polymer ist, das aus der

Gruppe ausgewählt ist, die PolyMilchsäure, Polyglykolsäure, Polycaprolakton und deren zugeordnete Copolymere umfaßt.

12. Intralumen-Stent nach einem der Ansprüche 1 bis 9, worin der Körperabschnitt aus einem Material gebildet ist, welches biokompatibel ist und aus der Gruppe ausgewählt ist, die die Familie linearer aliphatischer Polyester, Polyorthoester, Polyanhydrid, Polydioxanon, Polyhydroxybutyrat, rostfreien Stahl, Nickel-Titan, Platin, Nitinol, Tantal und Gold umfaßt.

13. Intralumen-Stent nach einem der vorhergehenden Ansprüche, worin der Körperabschnitt aus einem Material gebildet ist, das ein therapeutisches Mittel enthält.

14. Intralumen-Stent nach einem der vorhergehenden Ansprüche, worin der Körper aus einem zu einem Zylinder geformten Material gebildet ist, der eine Längsachse und zwei entlang der Längsachse zueinander im Abstand liegende Enden (55) aufweist, wobei die Enden (55) abgeschrägt sind, um zu ermöglichen, daß der Stent (10) an seinen Enden (55) flexibler ist.

15. Intralumen-Stent nach einem der vorhergehenden Ansprüche, worin der Körperabschnitt aus einem Material gebildet ist, das strahlungsundurchlässig ist.

Revendications

1. Dilatateur endoluminal expansible (10) implantable dans un vaisseau, comprenant :

   une partie de corps ;
   une pluralité de saillies (15), lesdites saillies (15) faisant saillie sur ladite partie de corps ; et une pluralité d'ouvertures (20) dans ladite partie de corps, plusieurs desdites saillies (15) s'engageant dans lesdites ouvertures (20) et plusieurs desdites saillies (15) s'engageant dans ledit vaisseau pour maintenir ledit dilatateur endoluminal (10) en place par rapport à celui-ci, caractérisé en ce que les saillies (15) sont découpées dans la partie de corps, les parties de la partie de corps ainsi enlevées définissant les ouvertures (20).

2. Dilatateur endoluminal selon la revendication 1, dans lequel :

   ladite partie de corps a une surface extérieure implantable adjacente à une paroi dudit vaisseau, et lesdites saillies (15) font saillie sur ladite surface extérieure de ladite partie de corps.

3. Dilatateur endoluminal selon la revendication 1 ou la revendication 2, dans lequel lesdites saillies (15) sont solidaires de ladite partie de corps et ont une forme essentiellement en "V", lesdites ouvertures (20) ayant essentiellement la forme desdites saillies (15).

4. Dilatateur endoluminal selon la revendication 3, dans lequel lesdites saillies (15) ont des côtés de longueur essentiellement égale qui forment un sommet, lesdits côtés étant espacés par un angle d'environ 90° au niveau dudit sommet.

5. Dilatateur endoluminal selon l'une quelconque des revendications précédentes, dans lequel lesdites saillies (15) sont espacées d'environ 4,801 x 10^{-4}m (0,0189 pouce) l'une de l'autre, et ont des côtés d'une longueur d'environ 3,556 x 10^{-4}m (0,014 pouce).

6. Dilatateur endoluminal selon l'une quelconque des revendications précédentes, dans lequel ledit dilatateur est fabriqué en une matière plastique choisie dans le groupe composé d'un polymère appartenant à la famille des polyesters aliphatiques linéaires et leurs copolymères associés.

7. Dilatateur endoluminal selon l'une quelconque des revendications précédentes, dans lequel lesdites saillies (15) sont espacées l'une de l'autre d'une manière essentiellement uniforme, pour former des rangées de saillies (15).

8. Dilatateur endoluminal selon l'une quelconque des revendications 1 à 6, dans lequel lesdites saillies (15) sont dispersées au hasard sur la totalité de ladite partie de corps.

9. Dilatateur endoluminal selon l'une quelconque des revendications précédentes, dans lequel ladite partie de corps est fabriquée en un matériau auquel on donne la forme d'un cylindre.

10. Dilatateur endoluminal selon le revendication 9, dans lequel ledit matériau est bioabsorbable.

11. Dilatateur endoluminal selon la revendication 9 ou la revendication 10, dans lequel ledit matériau est un polymère choisi dans le groupe composé de l'acide polylactique, l'acide polyglycolique, le polycaprolactone, et leurs copolymères associés.

12. Dilatateur endoluminal selon l'une quelconque des revendications 1 à 9, dans lequel ladite partie de corps est fabriquée en un matériau qui est biocompatible et choisi dans le groupe composé de la famille des polyesters aliphatiques linéaires, le polyorthoester, le polyanhydride, le polydioxanone,

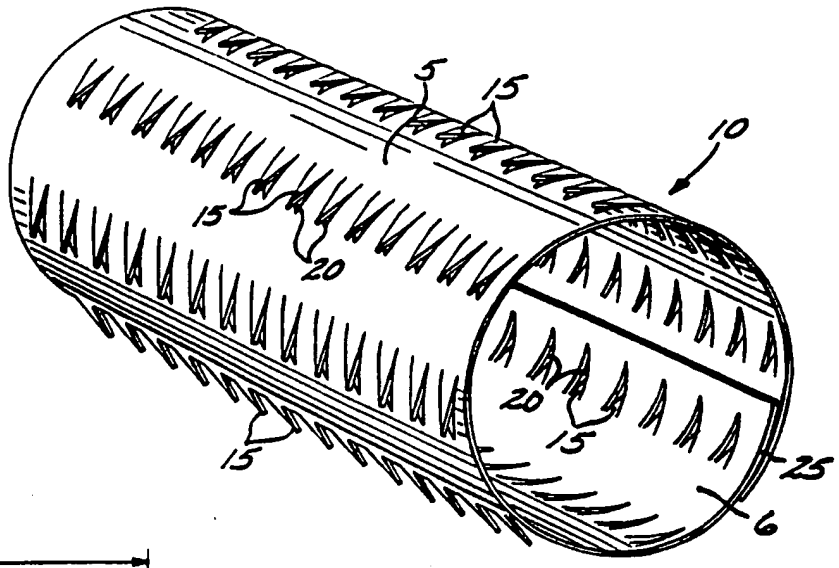
le polyhydroxybutyrate, l'acier inoxydable, le nickel-titane, le platine, le Nitinol, le tantale et l'or.

13. Dilatateur endoluminal selon l'une quelconque des revendications précédentes, dans lequel ladite partie de corps est fabriquée en un matériau contenant un agent thérapeutique.

14. Dilatateur endoluminal selon l'une quelconque des revendications précédentes, dans lequel ladite partie de corps est fabriquée en un matériau auquel on donne la forme d'un cylindre ayant un axe longitudinal et deux extrémités (55) espacées le long dudit axe longitudinal, lesdites extrémités (55) étant coniques pour permettre audit dilatateur (10) d'être plus souple au niveau desdites extrémités (55).

15. Dilatateur endoluminal selon l'une quelconque des revendications précédentes, dans lequel ladite partie de corps est fabriquée en un matériau qui est opaque aux rayons X.

FIG 1



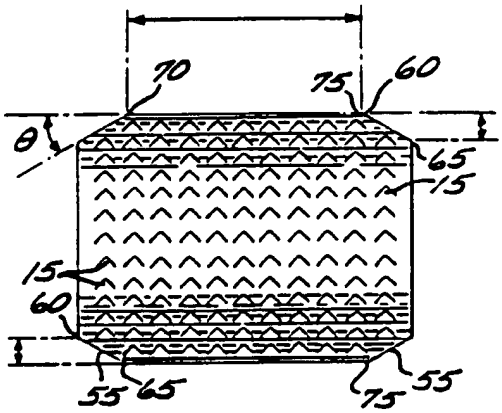


FIG.2

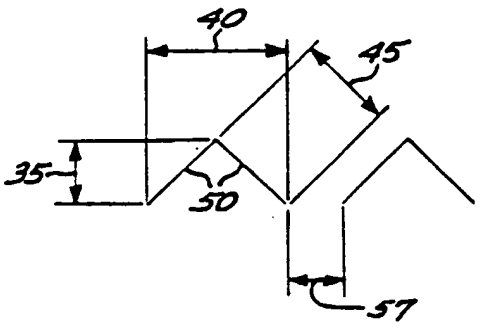


FIG.3

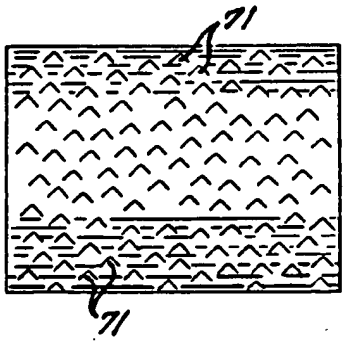


FIG.4